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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/440,371 | 11/12/1999 | GARY BLACKBURN | A-66566-3/RF | 2869 |

7590 05/27/2005

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| EXAMINER | |
|---|---|
| NOGUEROLA, ALEXANDER STEPHAN | |
| ART UNIT | PAPER NUMBER |
| 1753 | |

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/440,371 | BLACKBURN ET AL. | |
| | Examiner | Art Unit | |
| | ALEX NOGUEROLA | 1753 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *45-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/17/2000*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS of 9/21/2004*.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cheney, II et al. (US 5,391,250) ("Cheney") in view of Diebold et al. (US 5,437,999) ("Diebold").

Cheney discloses a method of making a substrate comprising a plurality of gold electrodes (abstract; Figures 1 and 2; and col. 4:25-35) comprising

a) coating an adhesion metal onto a substrate (col. 4:25-35);

b) coating gold onto the adhesion metal (col. 4:25-35); and

c) forming a pattern comprising the plurality of electrodes and associated interconnects using lithography (col. 4:36-50 and Figures 1-10).

Cheney does not mention using a fiberglass substrate; but uses polyimide substrate. See col. 3:65-68. It should be noted that Cheney does disclose using a fiberglass adhesive on the substrate. See col. 3:68 – col. 4:4.

Diebold discloses that fiberglass was conventionally used as a substrate in making printed circuit boards having gold coated onto an adhesion layer and polyimide was conventionally used in making flex circuits having a gold coating on an adhesion layer. See col. 1:37-51. More especially, Diebold further teaches making a biosensor, which is what Cheney makes, using a fiberglass substrate having a copper adhesion layer (col. 7:8-14). Since, as shown by Diebold, fiberglass and polyimide were conventional substrates at the time of the invention for electrodes having gold coated on

an adhesion layer, barring a contrary showing the choice of fiberglass over polyimide was within the skill of one with ordinary skill in the art at the time of the invention. One with ordinary skill in the art at the time of the invention would select the electrode substrate based on factors such as electrical resistance (a good insulator), stiffness or flexibility, mechanical strength, and chemical inertness to chemicals to which it may be exposed.

5. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cheney, II et al. (US 5,391,250) ("Cheney") in view of Takada et al. (US 5,312,651) ("Takada").

Cheney discloses a method of making a substrate comprising a plurality of gold electrodes (abstract; Figures 1 and 2; and col. 4:25-35) comprising

a) coating an adhesion metal onto a substrate (col. 4:25-35);

b) coating gold onto the adhesion metal (col. 4:25-35); and

c) forming a pattern comprising the plurality of electrodes and associated interconnects using lithography (col. 4:36-50 and Figures 1-10).

Cheney does not mention using a fiberglass substrate; but uses polyimide substrate. See col. 3:65-68. It should be noted that Cheney does disclose using a fiberglass adhesive on the substrate. See col. 3:68 – col. 4:4.

Takada discloses making a printed circuit board, and thus electrodes with interconnects, using a fiberglass substrate. See col. 1:1-14 and col. 2:4-9. It would

have been obvious to one with ordinary skill in the art at the time of the invention to use a fiberglass substrate as taught by Takada in the invention of Cheney because as taught by Takada the resulting electrical laminate will have "excellent heat resistance, humidity resistance and strong adhesive strength." See col. 2:35-40.

6. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) ("Diebold") in view of Takada et al. (US 5,312,651) ("Takada").

Diebold discloses a method of making a substrate comprising a plurality of electrodes (col. 3:41-45, especially lines 43-45) comprising

a) coating gold onto a substrate (col. 12:56-58 and col. 5-56 – col. 6:1); and

b) forming an electrode pattern using photolithography (col. 6:4-16).

For this embodiment Diebold does not specifically mention providing an adhesion metal between the gold coating and the substrate and also using a fiberglass substrate. However, Diebold discloses several alternative methods for making the working, reference, and counter electrodes some of which specifically use an adhesion layer and a fiberglass substrate. The discussion in col. 3:50-65, for example, discloses using an adhesion layer when making a working, counter, or reference electrode. See also col. 9:9-10, which states that a thin anchor layer may or may not be used. It would have been obvious to one with ordinary skill in the art at the time of the invention use an adhesion layer in the method discussed in col. 12:56-58 and col. 5:56 – col. 6:1 as taught by col. 3:50-65 because as taught by col. 3:62-62, "The purpose of the thin

anchor layer is to increase adhesion between electrically conducting material **1** and thin support material **2**, as well as to stabilize the microstructure of electrically conducting material **1**." These are benefits that would also accrue in the embodiment of col. 12:56-58 and col. 5:56 – col. 6:1.

As for a fiberglass substrate, Diebold does disclose that a fiberglass substrate may be used in the embodiment of 12:56-58 and col. 5:56 – col. 6:1. See col. 5:68 – col. 6:1. Takada discloses making a printed circuit board, and thus electrodes with interconnects, using a fiberglass substrate. See col. 1:1-14 and col. 2:4-9. It would have been obvious to one with ordinary skill in the art at the time of the invention to use a fiberglass substrate as taught by Takada in the invention of Diebold because Diebold discloses that a fiberglass substrate may be used and as taught by Takada the resulting electrical laminate will have "excellent heat resistance, humidity resistance and strong adhesive strength." See col. 2:35-40.

As for a plurality of electrodes this is implied since the embodiment of col. 5:56 – col. 6:1 is a semicontinuous production method. See col. 5:59-62. in any event, it would have been obvious to pattern a plurality of electrodes as this would be just mere multiplication of parts; that is, mass-producing the sensor.

7. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheney in view of Diebold as applied to claim 45 above, and further in view of

Murthy ("Glucose oxidase bound to self-assembled monolayers of bis(4-pyridyl) disulfide at a gold electrode: Amperometric determination of glucose," Analytica Chimica Acta 363 (1998) 215-220) ("Murthy").

Addressing claim 46, Cheney as modified by Diebold does not mention adding a self-assembled monolayer to each electrode (working electrode). Murthy teaches adding a self-assembled monolayer to a gold working electrode. See the abstract. It would have been obvious to one with ordinary skill in the art at the time of the invention to add a self-assembled monolayer as taught by Murthy in the invention of Cheney as modified by Diebold because as taught by Murthy when the resulting sensor is used with glucose oxides to measure glucose, which is a disclosed use of the sensor of Cheney, the glucose sensor will "show satisfactory operational stability and a suppression of Faradaic response to dioxygen, hydrogen peroxide and ascorbic acid is noticed,". See the abstract of Murthy and col. 5:6-13 of Cheney. Furthermore, "[l]arge catalytic currents are observed with a linear response over a fairly wide range of glucose concentrations." See 4. Conclusions on page 220.

Addressing claim 47, the SAM in Cheney as modified by Diebold and Murthy comprises glucose oxidase, which "captures" glucose. See the Murthy abstract.

8. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheney in view of Takada as applied to claim 45 above, and further in view of

Murthy ("Glucose oxidase bound to self-assembled monolayers of bis(4-pyridyl) disulfide at a gold electrode: Amperometric determination of glucose," Analytica Chimica Acta 363 (1998) 215-220) ("Murthy").

Addressing claim 46, Cheney as modified by Takada does not mention adding a self-assembled monolayer to each electrode (working electrode). Murthy teaches adding a self-assembled monolayer to a gold working electrode. See the abstract. It would have been obvious to one with ordinary skill in the art at the time of the invention to add a self-assembled monolayer as taught by Murthy in the invention of Cheney as modified by Takada because as taught by Murthy when the resulting sensor is used with glucose oxides to measure glucose, which is a disclosed use of the sensor of Cheney, the glucose sensor will "show satisfactory operational stability and a suppression of Faradaic response to dioxygen, hydrogen peroxide and ascorbic acid is noticed,". See the abstract of Murthy and col. 5:6-13 of Cheney. Furthermore, "[l]arge catalytic currents are observed with a linear response over a fairly wide range of glucose concentrations." See 4. Conclusions on page 220.

Addressing claim 47, the SAM in Cheney as modified by Diebold and Murthy comprises glucose oxidase, which "captures" glucose. See the Murthy abstract.

9. Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheney in view of Diebold as applied to claim 45 above, and further in view of Kinnear et al. ("Direct Electron Transfer to *Escherichia coli* Fumurate Reductase in Self-Assembled Alkanethiol Monolayers on Gold Electrodes," Langmuir 1993, 9, 2255-2257) ("Kinnear I') and Kinnear et al. ("Redox enzymes immobilized in membrane-mimetic media on gold electrodes for applications in sensing and synthesis," Book of Abstracts, 211$^{th}$ ACS National Meeting, New Orleans, LA, March 24-28 (1996)) ("Kinnear II") .

Addressing claim 46, Cheney as modified by Diebold does not mention adding a self-assembled monolayer to each electrode (working electrode). Kinnear I teaches adding a self-assembled monolayer to a gold working electrode. See the title and abstract. It would have been obvious to one with ordinary skill in the art at the time of the invention to add a self-assembled monolayer as taught by Kinnear I in the invention of Cheney as modified by Diebold because as taught by Kinnear I their method is a simple one-step process that allows redox-active, membrane-bound sensor proteins to be created. See the first column on page 2257. As an example, Kinnear II shows that fructose dehydrogenase may be immobilized using the SAM of Kinnear I. The resulting fructose sensor "proved to be an impressive prototype fructose biosensor with response time on the order of 20s; current densities up to 10 $\mu$A cm2; and low susceptibility to important electroactive interferants, such as ascorbic acid found in fruit juice." See Kinnear II.

Addressing claim 47, the SAM in Cheney as modified by Diebold, Kinnear I, and Kinnear II may comprise fructose dehydrogenase, for example, oxidase, which "captures" fructose. See the first column on page 2257 of Kinnear I and see Kinnear II.

Addressing claim 48, the SAM in Kinnear I (and Kinnear II) is using an aqueous deposition step. See the first full paragraph in the first column on page 2256 of Kinnear I.

10. Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheney in view of Takada as applied to claim 45 above, and further in view of Kinnear et al. ("Direct Electron Transfer to *Escherichia coli* Fumurate Reductase in Self-Assembled Alkanethiol Monolayers on Gold Electrodes," Langmuir 1993, 9, 2255-2257) ("Kinnear I') and Kinnear et al. ("Redox enzymes immobilized in membrane-mimetic media on gold electrodes for applications in sensing and synthesis," Book of Abstracts, 211$^{th}$ ACS National Meeting, New Orleans, LA, March 24-28 (1996)) ("Kinnear II") .

Addressing claim 46, Cheney as modified by Takada does not mention adding a self-assembled monolayer to each electrode (working electrode). Kinnear I teaches adding a self-assembled monolayer to a gold working electrode. See the title and abstract. It would have been obvious to one with ordinary skill in the art at the time of

the invention to add a self-assembled monolayer as taught by Kinnear I in the invention of Cheney as modified by Takada because as taught by Kinnear I their method is a simple one-step process that allows redox-active, membrane-bound sensor proteins to be created. See the first column on page 2257. As an example, Kinnear II shows that fructose dehydrogenase may be immobilized using the SAM of Kinnear I. The resulting fructose sensor "proved to be an impressive prototype fructose biosensor with response time on the order of 20s; current densities up to 10 $\mu$A cm2; and low susceptibility to important electroactive interferants, such as ascorbic acid found in fruit juice." See Kinnear II.

Addressing claim 47, the SAM in Cheney as modified by Takada, Kinnear I, and Kinnear II may comprise fructose dehydrogenase, for example, oxidase, which "captures" fructose. See the first column on page 2257 of Kinnear I and see Kinnear II.

Addressing claim 48, the SAM in Kinnear I (and Kinnear II) is using an aqueous deposition step. See the first full paragraph in the first column on page 2256 of Kinnear I.

11. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cheney, II et al. (US 5,391,250) ("Cheney") in view of Murthy ("Glucose oxidase bound to self-assembled monolayers of bis(4-pyridyl) disulfide at a gold electrode: Amperometric determination of glucose," Analytica Chimica Acta 363 (1998) 215-220) ("Murthy").

Addressing claim 49, Cheney discloses a method of making a substrate comprising a plurality of gold

electrodes (abstract; Figures 1 and 2; and col. 4:25-35) comprising

a) coating an adhesion metal onto a substrate (col. 4:25-35);

b) coating gold onto the adhesion metal (col. 4:25-35); and

c) forming a pattern comprising the plurality of electrodes and associated interconnects using photolithography (col. 4:36-50 and Figures 1-10).

Cheney does not mention adding a self-assembled monolayer to each electrode (working electrode). Murthy teaches adding a self-assembled monolayer to a gold working electrode. See the abstract. It would have been obvious to one with ordinary skill in the art at the time of the invention to add a self-assembled monolayer as taught by Murthy in the invention of Cheney because as taught by Murthy when the resulting sensor is used with glucose oxides to measure glucose, which is a disclosed use of the sensor of Cheney, the glucose sensor will "show satisfactory operational stability and a suppression of Faradaic response to dioxygen, hydrogen peroxide and ascorbic acid is noticed,". See the abstract of Murthy and col. 5:6-13 of Cheney. Furthermore, "[l]arge catalytic currents are observed with a linear response over a fairly wide range of glucose concentrations." See 4. Conclusions on page 220. Note that the SAM in

Cheney as modified by Diebold and Murthy comprises glucose oxidase, which "captures" glucose. See the Murthy abstract.

12. Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheney, II et al. (US 5,391,250) ("Cheney") in view of Kinnear et al. ("Direct Electron Transfer to *Escherichia coli* Fumurate Reductase in Self-Assembled Alkanethiol Monolayers on Gold Electrodes," Langmuir 1993, 9, 2255-2257) ("Kinnear I') and Kinnear et al. ("Redox enzymes immobilized in membrane-mimetic media on gold electrodes for applications in sensing and synthesis," Book of Abstracts, 211$^{th}$ ACS National Meeting, New Orleans, LA, March 24-28 (1996)) ("Kinnear II").

Addressing claim 49, Cheney discloses a method of making a substrate comprising a plurality of gold

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a) coating an adhesion metal onto a substrate (col. 4:25-35);

b) coating gold onto the adhesion metal (col. 4:25-35); and

c) forming a pattern comprising the plurality of electrodes and associated interconnects using photolithography (col. 4:36-50 and Figures 1-10).

Cheney does not mention adding a self-assembled monolayer to each electrode (working electrode). Kinnear I teaches adding a self-assembled monolayer to a gold working electrode. See the title and abstract. It would have been obvious to one with ordinary skill in the art at the time of the invention to add a self-assembled monolayer as

taught by Kinnear I in the invention of Cheney because as taught by Kinnear I their method is a simple one-step process that allows redox-active, membrane-bound sensor proteins to be created. See the first column on page 2257. As an example, Kinnear II shows that fructose dehydrogenase may be immobilized using the SAM of Kinnear I. The resulting fructose sensor "proved to be an impressive prototype fructose biosensor with response time on the order of 20s; current densities up to 10 $\mu$A cm2; and low susceptibility to important electroactive interferants, such as ascorbic acid found in fruit juice." See Kinnear II. Note that the SAM in Cheney as modified by Diebold, Kinnear I, and Kinnear II may comprise fructose dehydrogenase, for example, oxidase, which "captures" fructose. See the first column on page 2257 of Kinnear I and see Kinnear II.

Addressing claim 50, the SAM in Kinnear I (and Kinnear II) is using an aqueous deposition step. See the first full paragraph in the first column on page 2256 of Kinnear I.

***Information Disclosure Statement***

13. The information disclosure statement filed March 17, 2000 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The following references are missing from U.S. Application No.09/134,058

HH (sheet 2 of 11) – JP abstract 63-238166

1 (sheet 5 of 11) - Albers et al.

3 (sheet 5 of 11) – Aizawa et al.

62 (sheet 8 of 11) – Lincoln et al.

81 (sheet 9 of 11) – Reimers et al.

94 (sheet 10 of 11) – Takeda et al.

112 (sheet 11 of 11) – Derwent Publications Ltd. XP002124777

114 (sheet 11 of 11) – Pontius et al.

116 (sheet 11 of 11) – Kohne et al.

119 (sheet 11 of 11) – Műller et al.

120 (sheet 11 of 11) – Műller et al.

121 (sheet 11 of 11) – Gingeras et al.

123 (sheet 11 of 11) – Amasino et al.

124 (sheet 11 of 11) - Herne et al.

125 (sheet 11 of 11) – Steel et al.

126 (sheet 11 of 11) – Finklea

127 (sheet 11 of 11) – Beattie et al.

128 (sheet 11 of 11) – Docktycz et al.

129 (sheet 11 of 11) – Maldonado-Rodriguez et al.

130 (sheet 11 of 11) – Eggers et al.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Nogueróla
Primary Examiner
AU 1753
May 24, 2005